

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

UNOMEDICAL A/S,)
vs.)
SMITHS MEDICAL MD, INC.,)

Plaintiff,) CASE NO. 1:09-CV-04375
vs.) Judge John W. Darrah
Defendant.) Magistrate Judge Sidney I. Schenkier

)

**SMITHS MEDICAL ASD, INC.'S OPPOSITION TO UNOMEDICAL'S MOTION TO
STRIKE SMITHS' FOURTH, SEVENTH, AND NINTH AFFIRMATIVE DEFENSES
AND TO DISMISS SMITHS' NON-PATENT COUNTERCLAIMS**

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INTRODUCTION

Defendant Smiths Medical ASD, Inc. (“Smiths”) respectfully submits this opposition to plaintiff Unomedical A/S’s (“Unomedical’s”) Motion to Strike Smiths’ Fourth, Seventh and Ninth Affirmative Defenses and to Dismiss Smiths’ Non-Patent Counterclaims. Unomedical’s motion is premised on the mistaken belief that the pleadings must themselves provide conclusive and uncontested proof that Smiths is entitled to the relief it requests. This is not the case. Rather, Rules 8(a) and 9(b) simply require that Smiths’ pleadings provide Unomedical with notice of the basis of Smiths’ claims. *Swanson v. Citibank, N.A.*, 614 F.3d 400, 403-04 (7th Cir. 2010) (noting that well pled claims simply need to provide “fair notice”); *see also Bissessur v. Ind. Univ. Bd. of Trs.*, 581 F.3d 599, 603 (7th Cir. 2009) (“Our system operates on a notice pleading standard; *Twombly* and its progeny do not change this fact.”). All of Smiths’ affirmative defenses and counterclaims – including the inequitable conduct, patent misuse, antitrust, false advertising, and tortious interference claims at issue here – include more than enough facts to put Unomedical on notice of the conduct that serves as the basis of Smiths’ allegations.

As a consequence of its disregard of the underlying purpose of Rules 8(a) and 9(b), Unomedical’s motion amounts to little more than a request that the Court enter judgment as a matter of law without first allowing for discovery. For instance, Unomedical repeatedly asks the Court to rule that Smiths: has failed to “establish” that Unomedical acted in bad faith (*see, e.g.,* Unomedical Br., D.I. 141 at 20), has not presented facts which “establish” that Unomedical engaged in false advertising (*id.* at 22), and has not met its burden in “[e]stablishing” that Unomedical’s actions were objectively and subjectively baseless (*see id.* at 15, 22). These and other similar arguments seek a ruling premised on a weighing of the evidence and have no place

in a motion to dismiss. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007); *see also Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009).

Contrary to Unomedical's approach, when deciding a motion to dismiss, all well pled allegations in the claims at issue must be taken as true and viewed in the light most favorable to their proponent. *See Warth v. Seldin*, 422 U.S. 490, 501 (1975); *Killingsworth v. HSBC Bank Nev.*, N.A., 507 F.3d 614, 617 (7th Cir. 2007). As a result, it is only necessary for Smiths to plead "enough facts to state a claim to relief that is *plausible* on its face." *Twombly*, 550 U.S. at 570 (emphasis added); *see also Iqbal*, 129 S. Ct. at 1949. This "does not imply that the district court should decide whose version to believe, or which version is more likely than not." *Swanson*, 614 F.3d at 404. As long as a claim is "plausible," it properly survives a motion to dismiss for failure to state a claim even if it is "improbable" and even if the possibility of recovery is extremely "remote and unlikely." *Twombly*, 550 U.S. at 556. Smiths' various defenses and counterclaims clear these hurdles with room to spare.

Even if the Court finds that Unomedical's motion to dismiss or strike has merit (it does not), Smiths is in possession of additional facts which provide further illumination into the activities underlying its defenses and counterclaims. As a result, Smiths respectfully requests that in the event the Court grants Unomedical's motion in whole or in part, that Smiths' defenses and counterclaims be struck or dismissed without prejudice and that Smiths be granted leave to file further amended pleadings to include these additional facts. *See, e.g., Redfield v. Cont'l Cas. Corp.*, 818 F.2d 596, 609-10 (7th Cir.1987) (holding that failure to provide adequate notice in pleadings should not normally warrant a dismissal with prejudice); *Bobbitt v. Victorian House, Inc.*, 532 F. Supp. 734, 737 (N.D. Ill. 1982) ("Any defense inadequately pleaded will be dismissed *without* prejudice to enable defendants to correct ... technical deficienc[ies].").

ARGUMENT

I. Smiths' Inequitable Conduct Affirmative Defense Is Adequately Pled

A. The Basis of Smiths' Inequitable Conduct Defense

Smiths' ninth affirmative defense alleges that the '493 patent is unenforceable due to inequitable conduct that occurred during prosecution. (*See* D.I. 19 at ¶ 22.) In support of this defense, Smiths alleged that Jane Doe, the lawyer who prosecuted the '493 patent, intentionally hid three references from the Patent Office – U.S. Patent Nos. 5,451,210 ("the '210 patent"), 5,248,301 ("the '301 patent"), and 6,613,064 ("the '064 patent") – by burying those references in the middle of over 460 other less material references submitted during prosecution. (*Id.* at ¶¶ 22(A), (B), (C), (D).) Smiths also noted that Jane Doe not only buried the highly pertinent '210, '301, and '064 patents, but also refused to respond to the examiner's request that the applicants "point out any particular references in the IDS which they [believe] may be of particular relevance to the instant claimed invention." (*Id.* at ¶ 22(D).) Finally, Smiths noted elsewhere that certain of the other 460 references submitted by Jane Doe were facially immaterial and that this further "evidences Unomedical's bad-faith, deceptive burying of material references." (*Id.* at ¶ 103.)

B. Unomedical Is Asking This Court to Rule on the Strength of Evidence, Rather than the Sufficiency of the Notice Provided in the Pleadings.

Unomedical argues that Smiths has failed to plead its inequitable conduct defense with sufficient particularity because it did not adequately "show[]" who engaged in the alleged inequitable conduct, that Unomedical acted with an intent to deceive (*see* Unomedical Br., D.I. 141 at 5-7), that the buried references are not merely cumulative (*id.* at 9), or that Unomedical was aware of the relevant portions of the buried references at the time they were hidden (*id.* at 10). Unomedical also appears to question whether the burying of highly pertinent prior art

references in an enormous quantity of immaterial references (as Unomedical did here) can ever constitute inequitable conduct. (*See id.* at 6-9.) None of Unomedical’s arguments supports the striking of Smiths’ inequitable conduct defense.

“[T]o plead the ‘circumstances’ of inequitable conduct with the requisite ‘particularity’ under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). While the answer and counterclaims must plead that the prior art was material and non-cumulative (which Smiths did here), “the pertinent inquiry on Plaintiffs’ motion to dismiss is not whether Defendants used certain magic words, but whether Defendants pled the who, what, when, where, why, and how of the allegedly material omissions in sufficient detail to give Plaintiffs fair notice of the basis for their inequitable conduct claims.” *Bone Care Int’l, LLC v. Pentech Pharms., Inc.*, No. 08-cv-1083, 2010 U.S. Dist. LEXIS 39984, at *20 (N.D. Ill. Apr. 23, 2010). Rule 9(b) “should not be read as a mere formalism, decoupled from the general rule that a pleading must only be so detailed as is necessary to provide a defendant with sufficient notice to defend against the pleading’s claims.” *Id.* (quoting *United States v. Ford Motor Co.*, 532 F.3d 496, 503 (6th Cir. 2008)).

1. Smiths Has Sufficiently Pled “Who” Committed Inequitable Conduct: Jane Doe, the Attorney Who Prosecuted the ’493 Patent

Smiths’ defense clearly identified “who” knowingly buried material information: Jane Doe, the attorney who prosecuted the patent for Unomedical and who is listed by the ’493 patent’s publicly available application materials.¹ (D.I. 19 at ¶ 22). Specifically identifying an

¹ The general reference to “Unomedical and/or those associated with the prosecution of the ’493 patent,” that Unomedical points to is in the part of the answer alleging monopolization under the Sherman Act, not inequitable conduct. (*See* D.I. 19 at ¶¶ 104-105.)

individual in this manner is sufficient to satisfy the “who” requirement of Rule 9(b).² *Braun Corp. v. Vantage Mobility Int’l, LLC*, No. 2:06-CV-50, 2010 U.S. Dist. LEXIS 6839, at *16-17 (N.D. Ind. Jan. 27, 2010); *Lincoln Nat’l Life v. Jackson Nat’l Life Ins. Co.*, No. 1:07-CV-265, 2010 U.S. Dist. LEXIS 43687, at *24 (N.D. Ind. May 3, 2010); *see also Exergen*, 575 F.3d at 1329. Unomedical cannot credibly challenge that Smiths has adequately pled at least this portion of its inequitable conduct defense.

2. Smiths Has Sufficiently Pled “How” Jane Doe Committed Inequitable Conduct: By Burying Highly Material Prior Art References

Smiths’ answer alleges that Jane Doe engaged in inequitable conduct by burying the highly pertinent references in a raft of other irrelevant submitted material. (*See* D.I. 19 at ¶¶ 22(A), (B), (C), (D).) Rather than accept Smiths’ recitation of the facts as true, Unomedical attempts to litigate the substance of Smiths’ defense. In particular, it seems to argue that burying of pertinent references can never give rise to inequitable conduct. Many courts, however, have found that “burying” a particularly relevant reference within hundreds of other irrelevant references without bringing it to the examiner’s attention can constitute inequitable conduct. *See, e.g., CIVIX-DDI, LLC v. Hotels.com, L.P.*, 711 F.Supp.2d 839, 848-49 (N.D. Ill. 2010); *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F.Supp. 948, 964-65 (S.D. Fla. 1972); *see also Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995). And, contrary to Unomedical’s assertion, the MPEP still cautions the applicants about burying:

It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to applicant’s attention and/or are known to be of most significance.

² Unomedical does not appear to contest that it was appropriate for Smiths to identify the prosecuting attorney who engaged in the conduct at the heart of Smiths’ inequitable conduct defense as “Jane Doe,” likely because she is an attorney at its outside counsel’s law firm.

Manual of Patent Examining Procedure, § 2004 (8th Ed. Rev. 5, Aug. 2006) (The August 2006 MPEP was most recent when the examiner of the ‘493 patent requested specific identification of the most relevant prior art references, and Jane Doe failed to do so).

In *CIVIX-DDI*, the Northern District of Illinois denied a motion by the plaintiff for judgment on the pleadings of inequitable conduct on nearly the same factual situation present here. During the prosecution of the patents in that suit, plaintiff Civix submitted approximately 598 prior art references in what the Examiner described as “a mountain of material including approximately 244 U.S. patents, 64 published patent applications, and 290 non-patent references.” *CIVIX-DDI*, 711 F.Supp.2d at 848. Much like the ‘493 patent’s examiner, who was confronted with a similarly voluminous collection of prior art, the examiner of the patents at issue in *CIVIX-DDI* explained in an office action:

[An] applicant’s duty of disclosure of material information is not satisfied by presenting a patent examiner with “a mountain of largely irrelevant [material] from which he is *presumed* to have been able ... to have found the critical [material]. It ignores the real world conditions under which examiners work.” (italics in case examiner is quoting.)

Id. Like Jane Doe, Civix did not specifically identify the most relevant prior art references to its application. *Id.* at 848-49. There, the court rejected the very same arguments that Unomedical makes here. In particular, while Civix (like Unomedical) argued that it had no duty to highlight the references it believed to be most material or respond to an examiner request for this information, these were simply examples of “argument[s] concerning the underlying merits of Defendants’ allegations — not whether Defendants sufficiently alleged their counterclaims and affirmative defenses under Rule 9(b).” *Id.* at 849 (emphasis added).

While the cases Unomedical cites in support of its argument that “burying” cannot give rise to inequitable conduct may have some bearing in the event the parties file summary

judgment motions and this Court is called upon to decide the merits of those motions in view of the evidence adduced, they certainly do not require immediate dismissal based solely on the pleadings. For instance, in *Molins*, cited by Unomedical, the court noted that “‘burying’ a particularly material reference in a prior art statement containing a multiplicity of other references can be probative of bad faith.” 48 F.3d at 1184 (emphasis added). The court granted summary judgment for plaintiff on defendant’s inequitable claims, stating not that there could never be such a claim, but that based on the particular evidence of the case, the “circumstances ... do not present clear and convincing evidence of intent on the part of [the inventors] to conceal [the buried reference] from the PTO during the reexamination.” *Id.*

Similarly, in *PrimaTek II, LLC v. Polypap SARL*, 316 F.Supp.2d 693, 710 (S.D. Ill. 2004) and *Haney v. Timesavers, Inc.*, 900 F.Supp. 1378, 1382 (D. Ore. 1995), the courts held that on the particular evidence the parties had presented at trial or at the summary judgment stage, the defendants could not prove claims for inequitable conduct. And, the Federal Circuit in *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1326-27 (Fed. Cir. 2000) did not consider a situation where a disclosure failed to properly inform the examiner of a prior art reference because it was buried in a list of hundreds references (many of which, at best, are only marginally relevant). Finally, the District of Delaware in *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F.Supp. 2d 353, 358 (D. Del. 2009) did not apparently take into account section 2004 of the MPEP advising patent prosecutors to highlight the most relevant prior art references when submitting a long list, nor did it involve a case where the examiner explicitly requested such a specific identification, as is the case here.

In sum, the cases Unomedical cites do not show that Smiths could not conceivably state a claim for inequitable conduct based on the “burying” of pertinent prior art references. At best,

they show that if Smiths has no more evidence than what appears in the file history for the ‘493 patent after thorough discovery, it might not prevail on the merits. But, taking all the allegations in Smiths’ answer and counterclaims as true, the answer “support[s] a reasonable inference that [the] prosecuting attorney . . . attempted to deceive the PTO examiner by burying the highly relevant [’210, ’301, and ’064] prior art [references] in its submissions to the PTO.” *CIVIX-DDI*, 711 F.Supp.2d at 849 (citing *Exergen*, 575 F.3d at 1330).

3. Smiths Has Sufficiently Pled that the ‘210, ‘301, and ‘064 Patents Were Not Cumulative

Smiths’ Amended Answer states exactly how the ‘210, ’301, and ’064 patents would have disclosed or rendered obvious particular claims of the ‘493 patent. For instance, in its answer, Smiths noted the following:

- Figures 1-4 and columns 2 and 6-7 of the ‘210 patent disclose or render obvious every element of at least claim 1 of the ’493 patent by disclosing:

[A] container for facilitating placement of a medical device through a patient’s skin, the container comprising: a cylindrical housing in which there are defined a cap and a sleeve, said sleeve including a resting base having a planar surface configured for placement against a patient’s skin, said cap surrounding at least a portion of said sleeve and being axially slidably relative to said sleeve to substantially encase said sleeve when a sufficient pressure is exerted on said cap; a retaining member located within said housing, said retaining member having a needle secured thereto; a releasing member for releasing said needle from said retaining member when said cap is made to slide on said sleeve, thereby allowing the placement of said needle under the patient’s skin and the subsequent removal of said container; wherein the container is disposable and upon exertion of said pressure on said cap the force resulting from said pressure is transferred to said needle so that said needle is placed through the patient’s skin by means of said pressure exerted on said cap.

(D.I. 19 at ¶ 22(A).)

- Figures 2-9 and columns 3 and 5-9 of the ‘301 patent disclose or render obvious every element of at least claim 23 of the ‘493 patent by disclosing:

[A] container for facilitating placement of a cannula of a medical device through a patient's skin, the container comprising: a housing comprising a cap telescopically slidable over a sleeve, said sleeve defining an axis therethrough and including a resting base configured for placement against said patient's skin, said cap being slid able between a first position and a second position along the axis of said sleeve, wherein said cap substantially encases the axial length of said sleeve when said cap is in said second position; and a retaining member located within said housing, said retaining member having a piercing member secured thereto, said piercing member extending at least partially through said cannula for transcutaneous placement of said cannula; wherein said piercing member is concealed within said sleeve when said cap is in said first position and exposed from said sleeve when said cap is in said second position; wherein upon exertion of said pressure on said cap, said cap slides axially toward said patient's skin along said sleeve so that said piercing member is placed through said patient's skin and an end of said cannula is transcutaneously inserted and said medical device is retained on the patient and said piercing member secured to said retaining member is removed.

(*Id.* at ¶ 22(B).)

- Figures 1 and 4, as described in columns 1 and 2 of the ‘064 patent disclose or render obvious every element of at least claim 1 of the ‘493 patent by disclosing:

[A] cap that is axially slid able toward the base and the cap substantially encases the sleeve when a sufficient pressure is exerted on the cap.

(*Id.* at ¶ 22(C).) Additionally, Smiths attached an exhibit to its answer which identifies where the various limitations of independent claims 1 and 23 of the ‘493 patent can be found in the ‘210, ‘301, and ‘064 patents. (*See* Ex. 1 to D.I. 19.)

In order to establish that the prior art at issue is not cumulative of that already considered by the patent office, the Federal Circuit in *Exergen* only required the defendant to “identify the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record.” 575 F.3d at 1329. Here, Smiths alleges that certain prior art was

buried, and thus not explicitly considered by the examiner. Smiths has also alleged where in this buried prior art each of the various limitations required by the ‘493 patent’s claims can be found. The descriptions provided above and in Smiths’ answer certainly “explain both ‘why’ the withheld information is material and not cumulative, and ‘how’ an examiner would have used this information in assessing the patentability of the claims.” *Id.* (citing *Larson Mfg. Co. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1333 (Fed. Cir. 2009)). Indeed, since (as set forth in the pleadings) the buried references anticipate (i.e., describe each and every claim limitation of) the claims, they must necessarily be non-cumulative and more material than any reference that the Examiner actually considered. The Examiner would never have allowed the claims if he were aware of these or any other anticipatory reference. *See Bone Care Int’l*, 2010 U.S. Dist. LEXIS 39984, at *19-21 (rejecting argument that defendants failed to adequately plead that references were not cumulative. Allegations which “specif[ied] the claims … to which each omitted reference is relevant” were sufficient – “the clear implication is that if the references had been before the examiner..., the ... claims would have been rejected. That those claims were not rejected implies that no other information before the examiner compelled rejection, and thus that the five omitted references are not cumulative.”)

The pleading need only “put Plaintiffs on notice as to what information Defendants contend should have been before the examiner but wasn’t and how that information would have changed the examiner’s decision.” *Lincoln Nat’l Life*, 2010 U.S. Dist. LEXIS 43687, at *23 (quoting *Bone Care Int’l*, 2010 U.S. Dist. LEXIS 33984, at *6). Smiths’ inequitable conduct affirmative defense provides such notice.

4. Smiths Has Sufficiently Pled that Jane Doe Knew of the Material Prior Art References and Had an Intent to Deceive the PTO

Intent may be pleaded generally, and on information and belief. Fed. R. Civ. P.. 9(b); *Braun*, 2010 U.S. Dist. LEXIS 6839, at *14, 25-26. At the pleading stage, the defendant need only plead sufficient facts so that an inference of deceptive intent is reasonable. *Id.* at *26. Smiths' answer alleges that Jane Doe knew of the prior art references because she submitted them in an IDS (albeit buried among hundreds of irrelevant prior art references). Smiths' answer also highlights that these references facially disclose each and every limitation required by certain of the '493 patent's claims. Thus, it is reasonable to infer that Jane Doe knew they were highly material because they plainly disclosed the subject matter of the '493 patent.³ Moreover, Smiths' answer notes that Jane Doe refused to highlight the highly material prior art references despite the examiner's explicit request that she do so. It is certainly reasonable to infer from those facts that Jane Doe had an intent to deceive the PTO. *CIVIX-DDI*, 711 F.Supp.2d at 848-49.

This is not the same situation as in *Exergen*, where the pleading merely stated that the patentee "was aware" of the particular reference that was withheld (as opposed to buried the reference as in the present case). 575 F.3d at 1330; *see also Braun*, 2010 U.S. Dist. LEXIS 6839, at *22-23. "[T]he heightened pleading requirements of Rule 9(b) do not require that [the defendant] definitively prove the merits of its claim. What is determinative here is that [the plaintiff] was given fair notice of the basis for [the defendant's] inequitable conduct defense."

³ While Unomedical appears to argue that Jane Doe cannot be assumed to have been aware of the content of the prior art submitted to the Patent Office (*see* Unomedical Br., D.I. 141 at 10), if this were indeed the case it does not undermine Smiths' inequitable conduct affirmative defense. Rather, it would tend to show that Doe submitted hundreds of patents and publications to the Patent Office without any regard whatsoever for their relevance and bolsters Smiths' claim that it was Doe's intent to bury material references in bad faith in an attempt to overwhelm the examiner and avoid meritorious rejections based on the prior art.

Lincoln Nat'l Life, 2010 U.S. Dist. LEXIS 43687, at *25 (quoting *Western Geco v. Ion Geophysical Corp.*, No. 09-CV-1827, 2009 US Dist. LEXIS 100277, at *7 (S.D. Tex. Oct. 28, 2009)).

C. At This Point in Time, Smiths' Inequitable Conduct Claims Relate to the "Burying" of Prior Art References, Rendering Unomedical's Other Arguments Irrelevant

Unomedical seems to believe that Smiths is asserting an inequitable conduct defense based on Unomedical's alleged bad faith assertion of an invalid patent that was knowingly and improperly drafted in a manner that does not comply with § 112's written description requirement. But, these allegations underpin Smiths' antitrust counterclaims, not its inequitable conduct defense (at least at this point in time). At present, Smiths' pleadings allege inequitable conduct based only on the burying of the prior art discussed above. Thus, Unomedical's discussion of these other allegations and its contention that they fail to meet the standard set forth in *Exergen* simply have no relevance here.

II. Smiths' Counterclaims Are Also Adequately Pled Under Rules 8(a) and 9(b)

Unomedical next challenges Smiths' various non-patent law counterclaims. According to Unomedical, the allegations supporting these counterclaims do not provide it with adequate notice as required by Rules 8(a) and 9(b). Unomedical is wrong.

A. Smiths' Antitrust Claims (Counterclaims VI, VII, and VIII) Are Adequately Pled

Smiths' sixth, seventh, and eighth counterclaims find their root in Federal and Minnesota antitrust laws. In this regard, Smiths has alleged that Unomedical violated § 2 of the Sherman Act (*see D.I. 19 at ¶¶ 60-144*) and the Minnesota Antitrust Law of 1971 (*see id. at ¶¶ 145-151*) via its improper monopolization of and attempts to monopolize the infusion set market.

Smiths' antitrust counterclaims are premised on the same basic set of operative facts. For instance, Smiths alleged that the present litigation is a "sham" initiated for purely anticompetitive purposes because Unomedical knows (or should know) that the claims of the '493 patent cannot be both valid and infringed. (*See id.* at ¶ 110.) Smiths pointed out that Unomedical was aware (1) that the accused CLEO product is itself prior art and lacks certain claim limits and thus cannot infringe any valid claim (*see id.* at ¶¶ 62, 64, 71, 110), (2) that any claim of the '493 patent construed to apply to the CLEO product would fail to satisfy the requirements of 35 U.S.C. §112 (*see id.* at ¶¶ 68-70), and (3) that certain other prior art renders the claims of the '493 patent invalid (*see id.* at ¶¶ 104-109.) Smiths has also alleged a so-called "*Walker Process*" claim. In connection with this claim, Smiths alleged that Unomedical buried certain invalidating prior art references in a raft of other marginally relevant references submitted during the prosecution of the '493 patent and ignored an explicit request from the examiner to identify what it believed to be the most pertinent references. (*See id.* at ¶¶ 72-102.) This constituted inequitable conduct and, as a result, Unomedical is now improperly asserting and seeking to exclude competition with an unenforceable patent. (*See, e.g., id.* at ¶ 110.)

1. Smiths' Federal Antitrust Counterclaims (Counts VI and VII)

Regarding Smiths' "sham" litigation claims, Unomedical argues that Smiths has failed to plead facts showing that this case is objectively baseless. Smiths' antitrust counterclaim does, however, explicitly allege that Unomedical's assertion of the '493 patent here is "objectively baseless." (D.I. 19 at ¶ 61, 62, 110, 126.) Moreover, in support of this allegation, Smiths pointed to invalidating prior art, including the accused CLEO product itself (*see id.* at ¶ 64; *see also* ¶¶ 104-109), explained that the claims of the '493 patent are invalid for failing to satisfy the requirements of 35 U.S.C. § 112 (*see id.* at ¶ 68-69), and noted that the CLEO product cannot infringe any valid claim (*see id.* at ¶ 61, 71, 110). Since all of Smiths' well pled allegations are

to be taken as true (including its allegation that the ‘493 patent is invalid under §112, invalidated by various prior art, and not infringed), this is all that is required to defeat the Motion to Dismiss.

See, e.g., In re Androgel Antitrust Litig. (No. II), 687 F.Supp.2d 1371, 1380-81 (N.D. Ga. 2010) (noting that counterclaimants had adequately alleged a “sham litigation” in part by pointing to §112 deficiencies; whether those §112 arguments had merit “raises questions of fact that cannot be resolved at the pleading stage”).

While Unomedical attempts to characterize Smiths’ allegations as “garden-variety defenses of patent invalidity and non-infringement, and inequitable conduct which do not support a reasonable inference that this lawsuit is objectively baseless” (Unomedical Br., D.I. 141 at 16), this is not a relevant inquiry for a Rule 12(b)(6) motion. Since Smiths’ allegations regarding the baselessness of Unomedical’s infringement assertion are assumed to be true, whether or not the infringement assertion is actually “objectively baseless” is a question of fact that cannot be resolved in the context of a motion to dismiss. *See Hoffman-LaRoche Inc. v. Genpharm*, 50 F. Supp. 2d 367, 380 (D.N.J. 1999); *see also In re Relafen Antitrust Litig.*, 346 F.Supp.2d 349, 361 (D. Mass. 2004) (finding that “the facts tending to establish the existence or want of existence of probable cause were disputed, rendering the question inappropriate for decision as [a] matter of law”); *Skinder-Strauss Assocs. v. Mass. Continuing Legal Educ., Inc.*, 870 F.Supp. 8, 10 (D. Mass. 1994) (“Because [the defendant’s] counterclaims allege that the lawsuit filed by [the plaintiff] is objectively baseless and conceals an attempt to interfere directly with the business relationships of a competitor, the counterclaims adequately state a claim and should not be dismissed under Fed. R. Civ. P. 12(b)(6).”)

Unomedical also appears to argue that the mere fact that issued patents are presumed to be valid means that its infringement allegations cannot be baseless. (See Unomedical Br., D.I.

141 at 16-17.) Unomedical once again misses the mark. At the motion to dismiss stage, all well-pleaded allegations are assumed true and read in the light most favorable to the claimant. *See Killingsworth*, 507 F.3d at 617. Smiths has pled that the ‘493 patent is invalid. As a result, the presumption of validity does not require dismissal, as a presumption may be rebutted at trial. *See Grove Pharms., Inc. v. Par Pharm. Cos., Inc.*, No. 04-C-7007, 2006 WL 850873, at * 11 (N.D. Ill. March 28, 2006) (rejecting argument that presumption of validity required dismissal of sham litigation antitrust claim on motion to dismiss).

Finally, Unomedical appears to argue that Smiths’ counterclaims do not adequately allege that Unomedical acted with “bad faith.” According to Unomedical, “[n]o facts are pled to show that Unomedical had ‘knowledge’ that the claims are allegedly invalid, not infringed or unenforceable; or that Unomedical brought this lawsuit in bad faith.” (*See* Unomedical Br., D.I. 141 at 17-18.) This is simply not the case.

Importantly, Smiths is not required to prove via its counterclaims that Unomedical was actually aware of the invalidity, unenforceability, or noninfringement of the ‘493 patent’s claims at the time it filed suit; actual “proof” of fraudulent intent is not required at the pleadings stage. *See Gen. Ins. Co. of Am. v. Clark Mall Corp.*, No. 08-C-2787, 2010 U.S. Dist. LEXIS 98052, at *6-8 (N.D. Ill. Sept. 20, 2010); *see also In re Carmell*, 424 BR 401, 411-12 (Bankr. N.D. Ill. 2010) (“a [party] is not required to plead facts as to which they lack access prior to discovery”). Rather, “Rule 9(b)... specifically allows mental condition or intent to be averred generally.” *Gen. Ins. Co. of Am.*, 2010 U.S. Dist. LEXIS 98052, at *6. As a result, Smiths’ antitrust counterclaim is adequately pled as long as it includes allegations that provide some “basis for believing” that Smiths “could prove scienter.” *Id.*; *see also GMP Techs., LLC v. Zicam, LLC*, No. 08-C-7077, 2009 U.S. Dist. LEXIS 115523, at *8-10 (N.D. Ill. Dec. 9, 2009) (holding that

“allegations of ‘bad faith’ are subject to the general pleading requirements of Federal Rule of Civil Procedure 8(a)” and can be pled “generally”). “[C]ircumstances are all a complaint can point to.” *Gen. Ins. Co. of Am.*, 2010 U.S. Dist. LEXIS 98052, at *7.

Smiths did plead facts that, when viewed as a whole, give rise to a reasonable inference that Unomedical was aware of the invalidity of the ‘493 patent’s claims, and thus initiated the present action in bad faith. For instance, Smiths’ counterclaims highlight that Unomedical is the assignee of the ‘493 patent (*see D.I. 19 at ¶ 65*) and participated in its prosecution (*see id. at ¶¶ 67-68*). Thus, it is reasonable to assume that Unomedical knew (or should have known) that the claims are invalid under § 112 as Smiths alleges (*see id. at ¶¶ 68-70*). Further, Smiths pled facts indicating that Unomedical was aware of at least some of the invalidating prior art set forth in Smiths’ counterclaims prior to filing suit. For instance, Smiths alleged that by “at least early 2004 Unomedical learned of the CLEO product, and by at least late 2004 knew of its public sale.” (D.I. 19 at ¶ 64.) Together, these allegations give rise to a reasonable inference that Unomedical knew that the ‘493 patent’s claims are invalid, unenforceable, or not infringed. Smiths also noted that Unomedical’s fraudulent intent is further evidenced by Unomedical’s pre-filing activities. For instance, Smiths’ counterclaims allege that “Unomedical told Smiths’ customers and prospective customers, including at least Tandem Diabetes Care, that Smiths products infringe one or more valid Unomedical patents.” (*Id. at ¶ 120*.) This gives rise to a reasonable inference that Unomedical knew of the invalidity of the ‘493 patent’s claims, yet accused Smiths of infringement anyway in an attempt to dissuade Smiths’ prospective customers from purchasing the accused CLEO product and more than adequately establishes that Unomedical acted in bad faith. *See Gen. Ins. Co. of Am.*, 2010 U.S. Dist. LEXIS 98052, *5-7; *see also In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F. 3d 677, 693 (2nd Cir. 2009)

(noting that courts are “‘lenient in allowing scienter issues to withstand summary judgment based on fairly tenuous inferences,’ because such issues are ‘appropriate for resolution by the trier of fact’.... The same holds true for allowing such issues to survive motions to dismiss.”) (quoting *Press v. Chem. Inv. Servs. Corp.*, 166 F.3d 529, 538 (2nd Cir. 1999)); *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 363-64 (D.N.J. 2009) (noting that “when the predicate facts of an allegedly sham lawsuit are disputed, sham litigation claims should not be decided by the court as a matter of law” – in particular, “knowledge and intent are ‘disputed factual issue[s] that the Court [i]s duty-bound to submit to the jury.’”) (quoting *Relafen*, 346 F.Supp.2d at 362)

In connection with Smiths’ *Walker Process* antitrust claim, Unomedical argues that the counterclaim lacks “facts sufficient to show ‘a clear intent to deceive the examiner and thereby cause the PTO to grant an invalid patent’” (Unomedical Br., D.I. 141 at 14-15) and that Smiths has failed to “state any facts showing that the examiner relied upon the alleged misrepresentation or omission, and that but for this misrepresentation or omission, the ‘493 patent would not have issued” (*id.* at 15). This is nothing more than a rehash of Unomedical’s objections to Smiths’ inequitable conduct affirmative defense. As noted above, however, Smiths has adequately pled inequitable conduct. (*See supra* Section I.) Thus, Unomedical’s motion to dismiss Smiths’ *Walker Process* antitrust claims must also fail. *See, e.g., Somanetics Corp. v. CAS Med. Sys.*, No. 09-13110, 2010 U.S. Dist. LEXIS 17006, at *23 (E.D. Mich. Feb. 25, 2010) (denying motion to dismiss *Walker Process* claims because defendant’s “inequitable conduct allegations were adequately pled under Rule 9(b)”).

In view of the allegations outlined above, it cannot reasonably be disputed that Smiths’ antitrust counterclaim is adequately pled. And, even if the Court determines that Smiths’ claims are somehow lacking, Smiths is in possession of additional facts that further support its antitrust

claims (including, but not limited to, facts supporting its allegations that Unomedical’s infringement assertions are both objectively and subjectively baseless). As a result, Smiths should at the very least be given an opportunity to amend in the event Unomedical’s motion is granted.

2. Smiths’ Minnesota Antitrust Counterclaim

Unomedical concedes that the “Minnesota Antitrust Law of 1971 … is interpreted consistently with the federal antitrust statutes.” (Unomedical Br., D.I. 141 at 18.) As a result, since Smiths’ federal antitrust claims are adequately pled, its Minnesota claims are also sufficient. Unomedical’s motion to dismiss these claims should be denied.

B. Smiths’ False Advertising Claims (Counterclaims IV and V) Are Adequately Pled

Smiths’ fourth and fifth counterclaims allege that Unomedical made false statements in advertising in violation of the Lanham Act and the Minnesota Deceptive Trade Practices Act.

1. Smiths’ Federal Lanham Act Claims

Rather than point to any missing element, Unomedical argues that Smiths’ Lanham Act claim is “conclusory and overbroad” and does not “meet the Rule 9(b) pleading standard.” (Unomedical Br., D.I. 141 at 18-19.) In particular, Unomedical alleges that Smiths has failed to identify (1) “the person who made alleged misrepresentations,” (2) the “time (when) and place (where) of the alleged misrepresentation,” (3) “the medium or the method by which the alleged misrepresentations were made,” or (4) “the requisite content of the misrepresentation.” (*Id.*)

“[T]he who, what, when, and where aspects of the fraud,” however, “need not be related with exact details in the complaint as a journalist would hope to relate them to general public.” *In re Jacobs*, 403 B.R. 565, 573 (Bankr. N.D. Ill. 2009). Rather, it is only necessary to set forth a “basic outline” of fraud in order to alert the opposing party of the purported fraud he is defending

against. *Id.* at 573-74 (quoting *Caliber Partners, Ltd. v. Affeld*, 583 F.Supp. 1308, 1311 (N.D. Ill. 1984)). Smiths' counterclaims, when viewed as a whole, satisfy these requirements. In particular, Smiths provided the following factual details regarding Unomedical's misrepresentations:

- Who: Smiths does more than simply aver that “Unomedical has made false statements.” Rather, Smiths’ false advertising claims are premised on misrepresentations made by specific Unomedical personnel, including those in communication with “Smiths’ customers and prospective customers, including at least Tandem Diabetes Care” (*see D.I. 19* at ¶ 120) and other “third parties interested in purchasing Smiths’ products, product lines, and/or other business assets” (*id.* at ¶¶ 41, 48, 50-51). This is sufficient to put Unomedical on notice of the specific individual or individuals who made the misrepresentations at the heart of Smiths’ claim.
- What: Smiths has identified the content of the misrepresentations made by Unomedical. In particular, Unomedical has misrepresented to Smiths’ customers that “that Smiths’ products infringe one or more valid Unomedical patents” (*id.* at ¶ 120) and made “false statements … to the effect that Smiths’ products infringe the ‘493 patent’” (*id.* at ¶ 41).
- When: Smiths has also identified the time period during which Unomedical made the misrepresentations. This includes the time period “[p]rior to filing its Complaint in this suit” (*i.e.* from the ‘493 patent’s August 2008 issue date until August 2009). (*Id.* at ¶ 120.)
- Where: Smiths also identified where Unomedical made misrepresentations, *i.e.* in its discussions with “Smiths’ customers and prospective customers, including at least

Tandem Diabetes Care” (*id.*) and other “third parties interested in purchasing Smiths’ products, product lines, and/or other business assets” (*id.* at ¶ 41).

- How: Smiths has identified the method by which Unomedical made the misrepresentations in question: “Unomedical *told* Smiths’ customers and prospective customers” (*i.e.* orally communicated its infringement allegations) (*id.* at ¶ 120) and engaged in “word-of-mouth disparagement” through the inserter market’s “powerful, if informal, communication network.” (*Id.* at ¶ 43.)

Although it is not necessary at the pleadings stage, Smiths is in possession of further factual detail regarding the misrepresentations identified above and should at the very least be given an opportunity to amend in the event Unomedical’s motion is granted.

Unomedical also argues that “Smiths’ failure to plead bad faith also requires dismissal of its Lanham Act claim.” (Unomedical Br., D.I. 141 at 19-20.) According to Unomedical, Smiths simply alleges that “Unomedical knew that the ‘493 patent was invalid, unenforceable, and/or not infringed by Smiths.” (*Id.*) This, ignores, however, that other portions of Smiths’ counterclaims set forth facts indicating that Unomedical’s infringement assertions were in fact made in bad faith. (*See supra* Section II(A)(1).) Thus, since Smiths has adequately pled bad faith and set forth facts that put Unomedical on notice of the who, what, when, where, and how of the misrepresentations underlying this Lanham Act claim, Unomedical’s motion to dismiss this particular claim should be denied.

2. Smiths’ Minnesota Deceptive Trade Practice Claim

Unomedical simply notes that “Smiths’ MDPTA claim is fatally deficient for the same reasons as its Lanham Act claim.” (Unomedical Br., D.I. 141 at 20.) Since the Lanham Act

claim was adequately pled, however, Unomedical’s arguments regarding the Minnesota claim also fail and its motion to dismiss in this regard should be denied.⁴

C. Smiths’ Tortious Interference Claim (Counterclaim III) Is Adequately Pled

Smiths’ third counterclaim alleges that Unomedical intentionally and wrongly interfered with Smiths’ ability to enter into business relationships by making bad faith infringement allegations and engaging in several other bad faith conduct. (*See D.I. 19 at ¶¶ 38-46.*) Unomedical does not separately object to this counterclaim nor argue that it lacks any required element – other than to argue as it did in connection with the other counterclaims that Smiths “cannot establish that Unomedical’s claims of infringement … are objectively baseless, let alone made in bad faith.” (Unomedical Br., D.I. 141 at 22.) These arguments fail for the same reasons discussed above and Unomedical’s motion to dismiss Smiths’ tortious interference counterclaim should be denied.

III. Smiths’ Other Affirmative Defenses

Unomedical also asks the Court to strike Smiths’ fourth and seventh affirmative defense. Smiths’ fourth affirmative defense (*see D.I. 19 at ¶ 15*) is duplicative of its invalidity and unenforceability defenses. As a result, Smiths is willing to withdraw this defense if the Court believes this is necessary. Smiths’ seventh affirmative defense alleges that Unomedical has engaged in patent misuse. (*See D.I. 19 at ¶¶ 18-19.*) Once again, Unomedical does not separately object to this defense but instead notes that “[a]s with Smiths’ Lanham Act and tortious interference claims, its patent misuse claim requires a showing of bad faith.”

⁴ Unomedical also strangely argues that Smiths’ claim should be dismissed because “Minnesota law is inapplicable.” (Unomedical Br., D.I. 141 at 21.) Even if the applicability of Minnesota law were somehow an element that needs to be separately pled, Smiths has satisfied this requirement. Smiths’ counterclaims note that Smiths has a “principal place of business” in Minnesota (D.I. 19 at ¶ 23) and that it has been “damaged by Unomedical’s false, bad-faith statements in violation of Minn. Stat. § 325D.44” (*id.* at ¶ 58.) Since Smiths’ allegations are to be taken as true, Smiths has established that it has been injured in Minnesota and that Minnesota law applies.

(Unomedical Br., D.I. 141 at 23.) Since Smiths has adequately alleged bad faith in connection with its antitrust, false advertising, and tortious interference claims, Unomedical's motion to strike Smiths' patent misuse defense should also be denied.

CONCLUSION

For the reasons stated above, Smiths respectfully requests that the Court deny Unomedical's motion to strike Smiths' fourth, seventh, and ninth affirmative defenses and motion to dismiss Smiths' antitrust, false advertising, and tortious interference counterclaims.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 29, 2010, I caused a true and correct copy of the foregoing document(s) to be served via the ***Electronic Court Filing System (ECF)*** upon the following counsel of record:

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